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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HANI FARES, MARC CORNELL, PETER FOLTIS, and ISABELLE HANSENNE

Appeal 2009-014853
Application 10/646,300
Technology Center 1600

Decided: May 5, 2010

Before ERIC GRIMES, DONALD E. ADAMS, and DEMETRA J. MILLS, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a topical composition, which the Examiner has rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

"Hydrocortisone is used in many topical preparations as a treatment for temporary relief of itching" (Spec. 1). "Hydrocortisone has limited solubility in water. Thus, it is necessary to add co-solvents, surfactants, and/or complexing agents to obtain an aqueous solution of hydrocortisone." (*Id.*) The Specification discloses that "hydrocortisone is more soluble in pentylene glycol than other polyols. . . . Accordingly, compositions of the present invention may contain less total solvent compared to current products. Compositions of the present invention thus offer more aesthetic appeal." (*Id.* at 3.)

Claims 16-38 are on appeal. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claim 16 is representative and reads as follows:

> 16. A cosmetic or dermatological composition comprising hydrocortisone, or a derivative thereof, and a solvent for said hydrocortisone comprising pentylene glycol, wherein said hydrocortisone is present in an amount of about 0.01% to about 5% by weight of said composition.

I.

Issues

The Examiner has rejected claims 16-38 under 35 U.S.C. § 103(a) as obvious in view of Castro,[1] Cooper,[2] Quigley,[3] and Vollhardt[4] (Ans. 4). The Examiner finds that Castro discloses a composition for topical application comprising a pentylene glycol, and teaches that dermatologically active

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[1] Castro et al., US 6,113,888, Sept. 5, 2000
[2] Cooper et al., US 4,552,872, Nov. 12, 1985
[3] Quigley Jr. et al., US 6,075,056, June 13, 2000
[4] Vollhardt, US 6,274,124 B1, Aug. 14, 2001

agents including hydrocortisone can be added to it (Ans. 4). The Examiner finds that Cooper teaches a composition comprising diols and a corticosteroid such as hydrocortisone, in amounts encompassed by claim 16 (*id.* at 5). The Examiner concludes that it would have been obvious "to combine Castro et al. with Cooper et al. in view of Vollhardt" (*id.* at 6), which teaches formulations comprising a pentylene glycol and a cosmetic or dermatological active agent (*id.* at 5).

Appellants contend that the references do not support a prima facie case of obviousness because Castro discloses extensive lists of potential components for its composition and provides no reason to choose the specific components required by the claims (Appeal Br. 4, 6) and the secondary references do not make up for Castro's deficiency (*id.* at 6-8). Appellants also contend that they have provided evidence of unexpected results that overcomes any prima facie case of obviousness (*id.* at 9-12; Reply Br. 1-4).

The issues presented are:

(1) Does the evidence support the Examiner's conclusion that the cited references would have suggested the composition of claim 16?

and, if so,

(2) Have Appellants presented evidence of unexpected results that outweighs the evidence supporting a conclusion of obviousness?

Findings of Fact – Prima Facie Case

1. The Examiner finds, and Appellants do not dispute, that "1,2-pentanediol . . . is a species of the genus of pentylene glycols" (Ans. 8).

2. Castro discloses a self-tanning mousse composition comprising 1,2-pentanediol (Castro, col. 2, ll. 45-52).[5]

3. Castro describes two exemplary compositions containing 1,2-pentanediol (*id.* at col. 7, ll. 23-50 and col. 8, ll. 17-40).

4. Castro states that its composition can contain dermatologically active agents (*id.* at col. 3, ll. 41-48) "for treating wound healing, inflammation, acne, psoriasis, cutaneous aging, skin cancer, impetigo, herpes, chickenpox, dermatitis, pain, itching, and skin irritation" (*id.* at col. 4, ll. 61-64).

5. Castro states that "[e]xamples of such dermatologically active agents include hydrocortisone" (*id.* at col. 4, ll. 64-65).

6. Cooper discloses "compositions . . . for percutaneous delivery of corticosteroids" (Cooper, col. 5, ll. 6-8) including hydrocortisone (*id.* at col. 7, ll. 27-28, 46).

7. Cooper discloses that the "customary dosage level" for hydrocortisone is 0.1% to 1% (Cooper, col. 7, ll. 53-54; col. 8, l. 22).

Analysis – Prima facie case

Claim 16 is directed to a cosmetic composition comprising pentylene glycol and 0.01% to 5% hydrocortisone. Castro discloses a self-tanning composition containing 1,2-pentanediol (a pentylene glycol) and optionally hydrocortisone. Adding 0.1 to 1% hydrocortisone to the exemplary compositions disclosed by Castro would have been obvious to a person of ordinary skill in the art, because Castro suggests including hydrocortisone in

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[5] Castro refers to the compound as "1,2,-pentandiol" in several places but clearly intended "1,2-pentanediol"; cf. Castro, col. 5, l. 52.

its compositions and Cooper discloses that 0.1-1% is the customary dosage level for hydrocortisone in compositions for topical application (percutaneous delivery).

Appellants argue that Castro "literally discloses thousands of possible combinations and sub-combinations of optional ingredients, and requires the random selection of certain of these ingredients, for no apparent reason apart from knowledge of Appellants' invention" (Appeal Br. 4). However, as discussed above, Castro's exemplary embodiments would meet the limitations of claim 16 if they included hydrocortisone, Castro expressly suggests including hydrocortisone, and Cooper shows that claim 16 requires only the customary dosage level of hydrocortisone. We therefore agree with the Examiner that the cited references support a prima facie case of obviousness.

Findings of Fact – Unexpected Results

8. Cooper exemplifies compositions comprising hydrocortisone and propylene glycol (Cooper, col. 14, ll. 20-22), and hydrocortisone and butylene glycol (i.e., 1,2-butanediol or 1,3-butanediol) (*id.* at col. 14, ll. 40-46).

9. The Specification discloses the solubility of hydrocortisone in various solvents:

Glycerin:	0.4%
Isopropyl lauroyl sarcosinate:	2.0%
Propylene glycol:	4.0%
Butylene glycol:	4.8%
Pentylene glycol:	6.0%
Hexylene glycol:	3.2%

(Spec. 11, ¶ 24.)

10. The Specification states that "Applicants have found that the solubility of hydrocortisone in pentylene glycol is about 6%, . . . higher than the solubility of hydrocortisone in other glycols" (*id.* at 5, ¶ 13).

11. The Specification states that

> [o]ther solvents (or 'co-solvents'), particularly non-volatile solvents, may be present in the composition. . . . Due to the greater solubility of the active agents in pentylene glycol, the amount of the other solvents are significantly lower. . . . Relatively high amounts of glycols are undesirable from several standpoints, especially in terms of aesthetic appeal and tackiness. In contrast, compositions of the present invention are more aesthetically acceptable and have less tackiness.

(*Id.*)

12. The Specification exemplifies a cream composition and a gel composition, each comprising 1% hydrocortisone and 20% pentylene glycol (*id.* at 15-16).

13. The Specification discloses that the exemplified gel composition was compared to "Cortaid 1% Hydrocortisone Anti-Itch Cream (Pharmacia, Peapack, NJ); Rite Aid Hydrocortisone Cream 1% Plus 12 Moisturizers (Rite Aid, Harrisburg, PA); Cortizone 10 1% Hydrocortisone Anti-Itch Ointment and Cortizone 10 1% Hydrocortisone Anti-Itch Cream (Pfizer, Morris Plains, NJ)" (*id.* at 17, ¶ 31).

14. The Specification does not disclose how the components of the commercial products – other than their 1% hydrocortisone – compare to the components of the gel composition exemplified in the Specification.

15. The Specification discloses that "[d]issolution testing was performed" to measure release of the hydrocortisone-containing

compositions from cellulose nitrate membrane filters into saline solution (*id.* at 17, ¶ 32).

16. The Specification discloses that the results of the dissolution testing are shown in Figure 1, reproduced below:

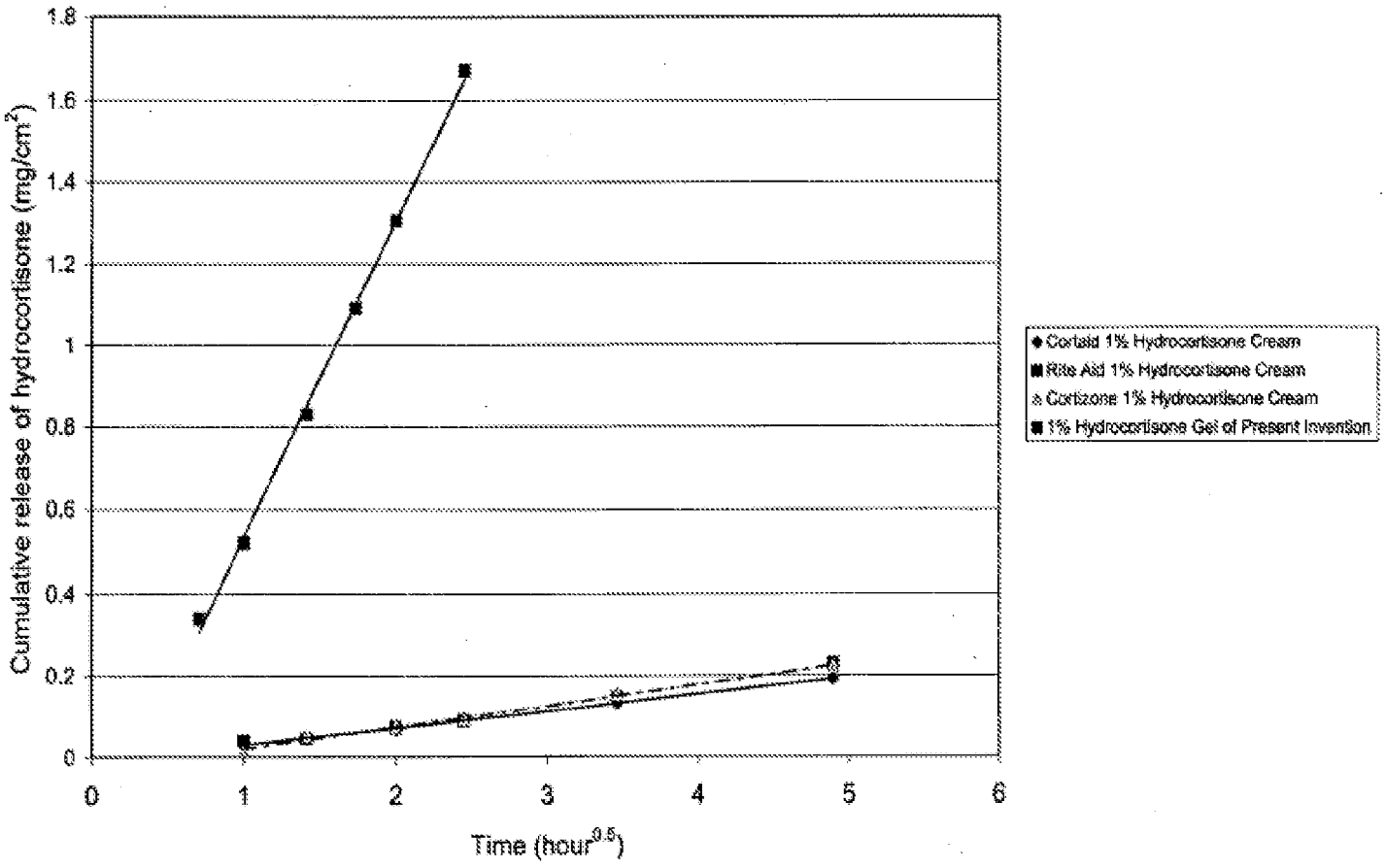

Figure 1 shows a comparison of "1% Hydrocortisone Gel of Present Invention" with three commercially available 1% hydrocortisone creams.

17. The Specification concludes that "compositions of the present invention provide greater availability of the active agent to penetrate the affected area on the skin or scalp, and thus provide greater bioavailability of the active agent" (*id.* at 18, ¶ 34).

18. Appellants have submitted a declaration under 37 C.F.R. § 1.132 by Hani Fares (executed March 28, 2005, copy included in the Evidence Appendix attached to the Appeal Brief).

19. Dr. Fares declares that he and his co-inventors "unexpectedly discovered that hydrocortisone is more soluble in pentylene glycol than in other diols. The claimed invention achieves unexpected results, namely greater aesthetic appeal, less tackiness, and greater penetration and bioavailability of hydrocortisone, compared to other commercial hydrocortisone topical formulations" (Fares Declaration 3).

Principles of Law – Unexpected Results

"One way for a patent applicant to rebut a *prima facie* case of obviousness is to make a showing of 'unexpected results,' i.e., to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected." *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995).

"Mere improvement in properties does not always suffice to show unexpected results. In our view, however, when an applicant demonstrates *substantially* improved results . . . and *states* that the results were *unexpected*, this should suffice to establish unexpected results *in the absence of* evidence to the contrary." *Id.* at 751 (emphasis in original).

"The evidence presented to rebut a *prima facie* case of obviousness must be commensurate in scope with the claims to which it pertains." *In re Dill*, 604 F.2d 1356, 1361 (CCPA 1979).

Analysis – Unexpected Results

Appellants contend that they "unexpected[ly] discover[ed] that hydrocortisone and its derivatives are more soluble in pentylene glycol than in other polyols such as glycerol, propylene glycol, butylene glycol, and hexylene glycol" (Appeal Br. 10-11). Appellants also contend that the Specification shows that "the release rate of hydrocortisone from a gel of the present invention was about 100 times greater than the various commercial products tested, none of which contains pentylene glycol" (*id.* at 11). Appellants conclude that "at least three unexpected benefits . . . flow from the combination of pentylene glycol and hydrocortisone and its derivatives, namely aesthetic appeal, less tackiness, and greater bioavailability" (*id.*).

We conclude that Appellants' evidence of unexpected results does not outweigh the evidence showing obviousness of the claimed composition. First, Appellants have not adequately established that the degree of increased solubility of hydrocortisone in pentylene glycol is greater than what would have been expected for different solvents. Appellants' evidence shows that hydrocortisone is 20% more soluble in butylene glycol than it is in propylene glycol (4.8% vs. 4.0%), and is 25% more soluble in pentylene glycol than it is in butylene glycol (6.0% vs. 4.8%) (FF 9).

The prior art disclosed compositions containing hydrocortisone and either propylene glycol or butylene glycol (FF 8). The increased solubility of hydrocortisone in pentylene glycol, compared to prior art compositions containing hydrocortisone and butylene glycol, thus appears to be within the range expected for different solvents. Dr. Fares' statement that the increased solubility in pentylene glycol was unexpected (FF 19) is not supported by

the evidence of record, or by reasoning based on science or logic, and is therefore not persuasive.

Second, even if it showed a difference so substantial as to be unexpected, Appellants' solubility evidence is not commensurate with the scope of the claims. Claim 16 encompasses compositions containing hydrocortisone and any amount of pentylene glycol, while the evidence of increased solubility applies only to compositions using pentylene glycol as the only solvent. The Specification itself concedes that "when the amount of pentylene glycol was reduced by two-thirds, the effectiveness of the solvent system was reduced by half" (Spec. 12, ¶ 25).

Finally, the evidence showing an increased dissolution rate for a gel composition encompassed by the claims, compared to three cream compositions, does not persuade us that the claimed composition has unexpectedly superior properties. The Specification does not disclose that components of the commercially available cream compositions, nor does it explain why the gel composition was chosen for comparison rather than the cream composition that was also exemplified in the Specification (FF 12). Thus, the Specification does not provide an adequate basis for concluding that the data shown in Figure 1 represent a valid comparison, such that the difference in dissolution rates should be attributed to the presence of pentylene glycol in the gel composition, rather than to some other difference between the claimed and commercial products.

Conclusions of Law

The evidence supports the Examiner's conclusion that the cited references would have suggested the composition of claim 16. Appellants

have not presented evidence of unexpected results that outweighs the evidence supporting a conclusion of obviousness.

SUMMARY

We affirm the rejection of claims 16-38 under 35 U.S.C. § 103(a) based on Castro, Cooper, Quigley, and Vollhardt.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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